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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,497	10/07/2004	Shunji Hayashi	Q84102	1554

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,497	HAYASHI ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/16/2009, 9/4/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed on 7/24/2009 is acknowledged.

Applicants' amendment of claim 6 has overcome the rejections under 35 USC 112, first and second paragraphs.

Claims 6-7 and 9-10 are being considered on the merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 6-7, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardiner et al. (1998, Development of a probiotic cheddar cheese containing human –derived Lactobacillus paracasei strains; hereinafter R1) in view of DE 1955833 (hereinafter R2) and Kimura et al. (EP 1 112 692 A1, hereinafter R3)

3. R1 reports the results of a research on the preparation of cheddar cheese containing live cultures of probiotic *Lactobacilli*. R1 confirms that L. paracasei strains grew and sustained high viability in cheese during ripening. (Abstract).

4. R1 discloses the process of producing the cheese where an inoculum of starter cultures is added to the pasteurized milk. In addition to the starter culture, a probiotic

culture such as *L. paracasei* is also added. Cheddar cheese is then produced according to the standard process known in the art. Preparation of the curd, cutting and cooking the curds are all standard processes as taught by R1. The curds are pressed and kept as pressed overnight. The cheese in then removed from mold, vacuum packed and ripened at 8C for approximately 8.5 months. (page 2193, Col. 1, Cheddar cheese manufacture).

5. While R1 discloses the addition of starter culture to the pasteurized milk, the addition of starter culture to raw milk is known in the cheese making art. Therefore, step (1) in claim 6 was known in the art at the time the invention was made.

6. Given that the cheese was kept under press at ambient temperature overnight, it is clear that the bacteria, in the cheese, were exposed to temperatures and duration as presently claimed. It is also obvious to those of skill in the art to incubate the cheese at growth temperature to allow the mesophilic microorganisms to proliferate in the cheese before cooling and storage.

7. R1 discloses that cheese made with *L. paracasei* contained high levels of these probiotic strains after 8 months of ripening with final counts of 10^7-10^8 CFU/g cheese. (page 2195, Col. 1, last two lines to Col. 2, first two lines).

8. R1 concludes that the probiotic L. paracasei strains incorporated into cheddar cheese are found to grow and proliferate to high cell numbers in cheese over 8 months even when they are added at a relatively small inoculum. R1 further discloses that the results of the present study indicate that Cheddar cheese offers potential as an effective vehicle for delivery of these strains to the consumer. (page 2198, Col. 1, Conclusion)

9. While R1 discloses the viability of certain probiotics in cheese as a delivery matrix, R1 is silent regarding the addition of yeast extract to the milk. R1 is also silent regarding the incorporation of *Lactobacillus gasseri* into the cheese.

10. R2 discloses a process where cheese of all types of improved storage life, higher yield and improved aroma are obtained by replacing or supplementing conventional cheese cultures with Bifidus bacteria and preferably adding growth activators such as yeast extract, yeast autolysate etc. to the milk. (Abstract).

11. Given that R2 discloses the use of yeast extract or yeast autolysate in order to support and activate the growth of the probiotic organisms, it is obvious that the yeast extract should be added to the milk before the formation of curd. It is also known in the art that adjuncts such as starter cultures, calcium chloride, any coloring (if used) must be added to the milk before the formation of curd. The addition of yeast extract to the milk before the formation of the curd will help a uniform distribution of the yeast extract in the body of milk so that microorganisms will grow uniformly and later will be distributed more uniformly in the cheese curd. Therefore, the addition of yeast extract to the raw milk at the same time or after adding the lactic acid bacteria starter to the raw milk and before formation of the curd was known in the art.

12. While R2 discloses the incorporation of probiotics such as Bifidus bacteria in cheese, R2 is silent regarding the incorporation of *Lactobacillus gasseri* in cheese.

13. R3 teaches the use of *Lactobacillus gasseri*, with a disinfection property against *Helicobacter pylori,* in foods [0001].

14. R3 characterizes their *Lactobacillus gasseri* OLL 2716 to have high survival when applied to food products (page 3, lines 20-21). They further disclose the storage temperature of $10^{\circ}C$ and viable count of more than 10^{7} cfu/ml of yogurt after 2 weeks (page 8, lines 5-7). Yogurt is a high water activity (a_w) food product compared to semi-hard or hard cheeses. Cheese, especially hard cheese, has a much lower water activity and under the conditions of lower water activity survival rate will be high. Consequently the limitation of claim 1 regarding the viable counts will depend on how many viable bacteria are initially present. The initial population will have a much higher survival rate when stored under the storage conditions of temperature as taught by R1.

15. R3 explains the use of *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) in foods (Abstract and [0013, 0014, 0015]). Given that this organism is exactly the same as the organism in claim 10, R3 teaches that the claimed organism can be used in foods. R3 discusses the use of Lactobacillus gasseri in foods, in food components and in combination with other foods [0017].

16. R1 discloses the incorporation of probiotics in cheese where they can have a high rate of viability and recommends using cheese as a suitable vehicle to deliver such probiotics to consumers. R2 teaches of the addition of yeast extract or yeast autolysate as a growth promoter of probiotics in cheese. R3 clearly discloses the anti *Helicobacter pylori* properties of Lactobacillus gasseri and how dairy foods may be used containing this probiotic. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to follow the teachings of R1 to make a cheese where yeast extract is added to the raw milk as a growth promoter for the

probiotic organisms as taught by R2 and incorporate *Lactobacillus gasseri* as an anti *Helicobacter pylori* agent, as taught by R3, into the cheese. One would do so to produce a cheese which can contain a high number of a probiotic organisms such as *Lactobacillus gasseri* and use it as an efficient matrix for delivery of probiotics to the consumers. Absent any evidence to the contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success to incorporate a probiotic organism such as *Lactobacillus gasseri* in cheese as presently claimed.

17. Claims 6-7 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable Gardiner et al. (1998, Development of a probiotic cheddar cheese containing human – derived Lactobacillus paracasei strains; hereinafter R1), DE 1955833 (hereinafter R2), Kimura et al. (EP 1 112 692 A1, hereinafter R3), further in view of Germond et al. (WO 0188150, hereinafter R4).

18. The disclosure by R1, R2 and R3 are hereby incorporated by reference as outlined in paragraphs 3-15 above. R1-R3 are silent regarding the incorporation of *Lactobacillus gasseri* in cheese.

19. R4 discloses the incorporation of *L. gasseri* in dairy products including cheese. (page 3, lines 28-30; page 6, lines 2-4; claims 8-11)

20. R4 discloses the food compositions containing the probiotic organisms including *L. gasseri*. Given that such food compositions retain the live organisms, it is clear that these probiotic organisms will be alive during the storage of the food compositions.

21. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to follow the teachings of R1, R2 and R3 to make a cheese where yeast extract is added, to the raw milk, as a growth promoter for the probiotic organisms and incorporate *Lactobacillus gasseri* as an anti *Helicobacter pylori* agent directly into the cheese as disclosed by R4. One would do so to produce a cheese which can contain a high number of a probiotic organism such as *Lactobacillus gasseri* and use it as an efficient matrix for delivery of probiotics to the consumers. Absent any evidence to the contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success to incorporate a probiotic organism in cheese as presently claimed.

Response to Arguments

Applicants' argument regarding the survival rate of the bacteria has been reviewed. That argument is not persuasive for the following reasons.

1. Applicants argue that R2 does not disclose or recognize the addition of yeast extract before formation of the curd and that R2 does not disclose or teach adding yeast extract to the raw milk at the same time or after adding the lactic acid bacteria to the raw milk, and before formation of the curd.

a. It is a routine practice in the art to add all adjuncts, when required, to the liquid milk before formation of curd. Please refer to paragraph 11 above. Adding starter culture to raw milk in also practiced in the art. Therefore, adding yeast extract to the raw milk at the same time or after the addition of starter culture is not a novelty. Further, R2

discloses that milk is mixed with 1.5% yeast autolyzate or yeast extract and sterilized. Therefore, it is clear yeast extract is being added to raw milk.

2. Applicants argue that it is not reasonable to assume all lactobacillus strains are expected to have the same growth rate and survival rate overtime when incorporated into cheese.

a. It is agreed that the lactobacilli may have different growth rate and survival rate during storage when incorporated into cheese. However, the incorporation of L. gasseri into cheese and its survival overtime was known at the time the invention was made. It was known that L. gasseri and other probiotics incorporated into cheese should have had an acceptable survival rate so that cheese could be an effective carrier for these probiotics. Please refer to paragraphs 19-20 above.

3.. Applicants argue that it is not easy to increase the number of lactic acid bacteria in cheese because water activity is low in cheese.

a. Attention is drawn to the following. Firstly, when survival is discussed, it should be addressed regarding the duration of time the cheese stays at storage, simply because one tries to have live organisms at the consumption point. It is true that one starts with a given number of bacteria at the beginning, however, what is left at the end of the storage time will determine the survival rate. Therefore, while the bacteria will proliferate at the beginning of the cheese making process, their viability and survival will depend on other dominating factors during storage such as low water activity, low oxidation-reduction in the environment, and low temperature of storage which cause a decrease in metabolic rate which will have a preserving effect.

As it was mentioned above, it is true that at the beginning of the process, the microorganisms should proliferate and increase in number, however, thereafter at storage temperature of below 10C, as presently claimed, there will be no growth and the microorganisms will survive if water activity is low (compared with liquid milk), if oxygen tension is low (anaerobic conditions in compressed cheese) and if storage temperature is low. Therefore, during storage, these factors will determine the viability and the survival of the microorganism in cheese.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,578,988 to Hori et al. This reference discloses the addition of starter culture to raw milk (Example 2).

JP 2001-000143-A: Incorporation of L. gasseri OLL 2716 into food products for anti H. pylori effect.

JP H08-116872-A: Promoting the proliferation of Lactobacilli.

JP H07-236484-A : Incorporating L. gasseri into cheese.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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